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Resolute's Stent-Thrombosis Risk Lasts Just 1 Month

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AT TRANSCATHETER CARDIOVASCULAR THERAPEUTICS 2012

VITALS

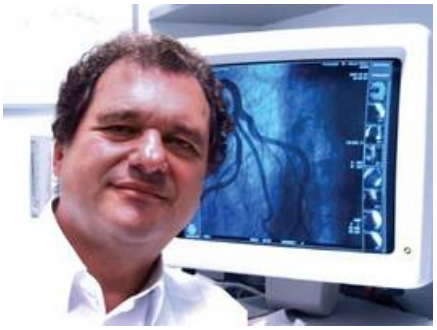
Major Finding: Interrupting dual antiplatelet therapy after receiving a Resolute stent was associated with stent thrombosis only in those who stopped in the first month (3%).

Data Source: Data came from a review of 4,934 patients who received a Resolute coronary stent.

Disclosures: The Resolute studies were funded by Medtronic, the company that markets the stent. Dr. Silber said that he has received research support from Medtronic, as well as from Abbott and Boston Scientific. Dr. Fontana is a Medtronic employee.

When patients who received a Resolute stent prematurely stopped their dual antiplatelet therapy, all the stent-thrombosis events that followed clustered in the patients who stopped their drugs during the first month after stent placement, in a review of nearly 5,000 patients.

The 1,076 Resolute recipients who interrupted their mandated treatment with aspirin and a thienopyridine included 169 patients who stopped during the first month after getting their stent. Five of these patients (3%) had stent thrombosis, compared with a 0.7% rate of stent thrombosis during the first month after placement among 3,858 patients who received a Resolute zotarolimus-eluting coronary stent and remained on their dual antiplatelet therapy (DAPT) for the prescribed 12 months, Dr. Sigmund Silber reported at Transcatheter Cardiovascular Therapeutics 2012.


Courtesy Dr. Sigmund Silber

Dr. Sigmund Silber

Among the remaining 907 patients who interrupted their DAPT sometime during months 2-12 after getting their stent, no additional episodes of stent thrombosis occurred. The 3,858 patients who remained on DAPT throughout the full 12 months of mandated treatment had eight additional stent thromboses, a 0.2% rate, said Dr. Silber, a cardiologist and professor at Ludwig-Maximilians University in Munich.

"If patients took DAPT for only 1 month, they had no increased risk for stent thrombosis" compared with patients who stayed on DAPT for 1 year. "This is a very surprising finding," Dr. Silber said in an interview.

"This was a post hoc analysis, and it does not mean that you can take patients who get a Resolute stent off of DAPT after 4 weeks. But if, for some reason, the patient has to come off of DAPT after 4 weeks, the risk of stent thrombosis is not as big as we had feared," he said.

This performance of the Resolute zotarolimus-eluting stent contrasts with the performance of first-generation drug-eluting coronary stents,

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which consistently showed elevated rates of stent thrombosis when DAPT was not maintained for at least 6 months after placement, he noted. In addition, review of experience with the Xience everolimus-eluting stent, another second-generation coronary stent, showed a similar pattern when DAPT was maintained for at least 3 months. But "as far as I know, no data were reported on Xience after 4 weeks," said Dr. Silber, who is also director of the Isar Heart Center in Munich.

Although this was a post hoc analysis, one message is clear, he said: "Physicians should do everything possible to continue DAPT during the first month." So far, it remains unclear whether interruption of DAPT followed by a restart led to any difference in the stent thrombosis rate compared with full discontinuation. An analysis that compares these two types of stoppages is in process.

In addition, the findings suggest running a prospective trial to test the efficacy and safety of using DAPT for 1 month in patients who receive a Resolute stent compared with patients who receive DAPT for 6 or 12 months, Dr. Silber said. But he acknowledged that this would be a challenging trial to run – randomizing patients to DAPT for just 1 month after placing a drug-eluting stent, plus enrolling several thousand patients. "Does anyone have the guts to do that?" he asked.

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Dec 2 - 4 Tel - Aviv,	Innovations in Cardiovascular Interventions (ICI)
Dec 5 - 8 Athens,	European Society of Cardiology (ESC): EUROECHO 2012
Dec 14 - 16 San Francisco, CA	University of California, San Francisco (UCSF): Advances in Heart Disease
Dec 14 - 16 New York, NY	American College of Cardiology (ACC): Annual New York Cardiovascular Symposium
Jan 14 - 18 Snowmass, CO	American College of Cardiology (ACC): Cardiovascular Conference at Snowmass
Jan 17 - 19 Boston, MA	Annual International Boston Atrial Fibrillation Symposium
Jan 28 - Feb 1 Maui, HI	Mayo Clinic: Arrhythmias & the Heart
Feb 6 - 8 Honolulu, HI	American Heart Association (AHA): International Stroke Conference (ISC)
Feb 23 - 26 Washington, DC	Cardiovascular Revascularization Therapies (CRT): CRT 2013

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